Paradigm for Addressing Drinking Water Contaminants As Groups to Enhance Public Health Protection

- EPA Draft Discussion Paper -

1. Introduction

On March 22, 2010, EPA Administrator Lisa P. Jackson announced a new drinking water strategy which outlines four principles to expand public health protection for drinking water. One of these principles is to address contaminants as group(s). EPA is seeking ways to better address contaminants in groups by working within the current regulatory framework so that enhancement of drinking water protection can be achieved more efficiently and cost-effectively.

EPA seeks input on this document from the general public, and interested stakeholders. This discussion paper provides background information on the current regulatory approach, how this approach might address contaminants as groups, possible factors for grouping contaminants, potential contaminant groups and regulatory mechanisms/options for addressing contaminant groups.

Issue Statement

The current regulatory framework for drinking water protection mainly focuses on assessing risks from exposure to individual contaminants. The administrative burden and high resource requirements of the current framework on Federal and State Governments as well as water utilities may make it difficult to effectively deal with an increasing number of new contaminants and the continuous accumulation of new information on these contaminants. Evaluating and addressing contaminants as groups during the regulatory process may better protect public health; consume less time and resources; account for risks from multiple contaminants; deal more effectively with an increasing number of emerging contaminants; and provide water systems with an opportunity to make better long-term decisions on capital investments.

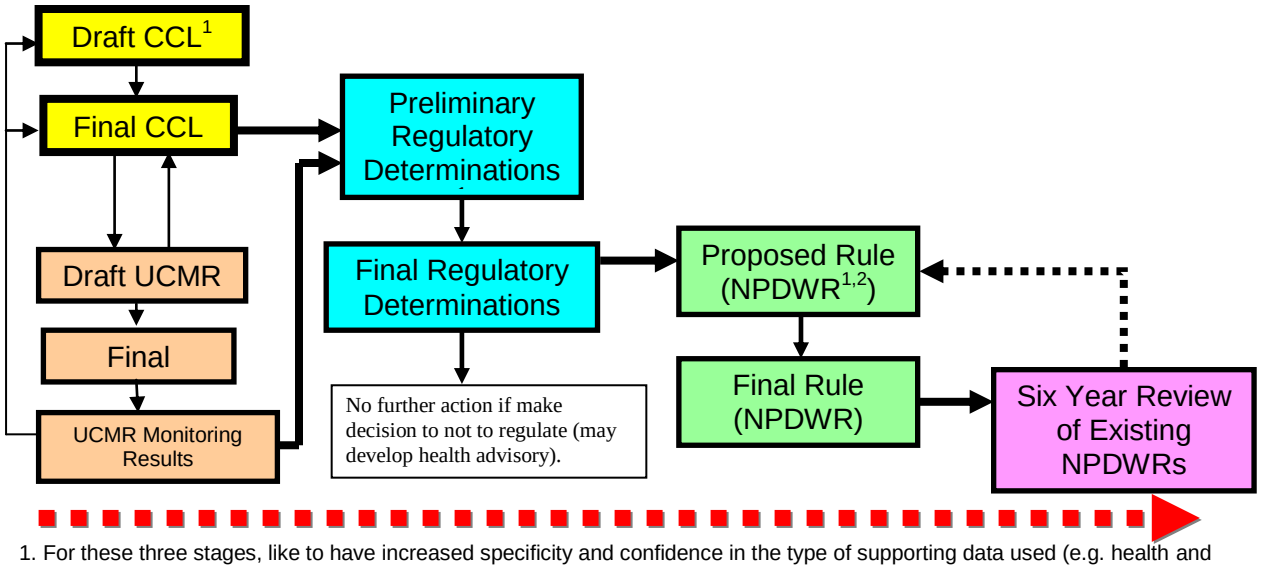
Background

EPA's regulatory framework for drinking water protection must fit within the requirements of the Safe Drinking Water Act (SDWA). SDWA requires EPA to undertake several actions to assess and manage the risks posed by drinking water contaminants. These actions include the Contaminant Candidate List development, the Unregulated Contaminant Monitoring Rules, Regulatory Determinations, National Primary Drinking Water Rule promulgation, and the Six Year Review of existing regulations. Exhibit 1 depicts the inter-relationships of these processes.

SDWA requires EPA to identify and list unregulated contaminants that may require a national primary drinking water regulation (NPDWR) in the future. EPA must periodically publish this list of unregulated contaminants (called the Contaminant Candidate List or CCL) and decide whether to regulate at least five or more contaminants on each list (called Regulatory Determinations). EPA also uses this list of unregulated contaminants to prioritize research and

data collection efforts to help the Agency determine whether it should regulate a specific contaminant.

Exhibit 1: Generalized Flow of Regulatory Processes



1. For these three stages, like to have increased specificity and confidence in the type of supporting data used (e.g. health and occurrence).
2. When setting the NPDWR, SDWA requires that we: (a) establish the MCLG, (b) set MCL as close as feasible to the MCLG, (d) if cannot establish an MCL (because no reliable/feasible method to measure), establish a Treatment Technique (TT), (d) consider maximizing health risk reduction benefits at a cost justified by the benefits in setting the standard.

A regulatory determination is a formal decision regarding whether EPA should initiate a rulemaking to develop an NPDWR for a specific contaminant. EPA makes regulatory determinations based on the best available information, including public and stakeholder input, and publishes these determinations in the Federal Register for public review and comment. SDWA requires EPA to publish a Maximum Contaminant Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines that all three of the following SDWA criteria are met –

- *The contaminant may have an adverse effect on the health of persons;*
- *The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and*
- *In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.*

In evaluating unregulated contaminants, EPA uses the Unregulated Contaminant Monitoring Regulation (UCMR) program to collect monitoring data from systems for contaminants that may

be present in drinking water. The contaminants listed for monitoring largely come from the CCL and the data obtained is utilized in the regulatory determinations process.

If the Agency decides to regulate a contaminant and develop an NPDWR, the 1996 SDWA Amendments require the Agency to consider the best available, peer reviewed science and data collected in accordance with accepted guidelines as well as a health risk reduction and cost/benefit analysis. The Agency must consider this information when setting the enforceable standards so the standards are both efficient and effective in protecting human health. This makes it possible for the Agency to set priorities that will allow Federal, State, and local resources to be targeted toward the drinking water problems of greatest public health concern.

When developing an NPDWR, SDWA requires the Agency to establish a **Maximum Contaminant Level Goal (MCLG)**, which is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MCLGs are non-enforceable public health goals. EPA considers the risk to sensitive subpopulations (infants, children, the elderly, and those with compromised immune systems) when setting an MCLG. Since MCLGs consider only public health and not the limits of detection and treatment technology, sometimes they are set at a level which water systems cannot meet. Typically, the Agency develops an MCLG for a single contaminant, but on occasions, has developed an MCLG for a group of contaminants such as alpha-emitting or beta-emitting radionuclides.

After the MCLG is developed, EPA sets an enforceable standard. In most cases, the standard is a **Maximum Contaminant Level (MCL)**. SDWA defines the MCL as the maximum permissible level of a contaminant or group of contaminants in drinking water which is delivered to any user of a public water system. SDWA requires EPA to set an MCL as close to the MCLG as feasible, or to identify a **Treatment Technique (TT)** that would prevent known or anticipated adverse effects on the health of persons to the extent feasible. SDWA defines "feasible" as the level that may be achieved "with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)" In addition, SDWA also requires EPA to specify an MCL that is economically and technologically feasible to attain in water from public water systems [§1401(1)(C)(ii)], including quality control and test procedures to insure compliance [§1401(1)(D)]. Analytical measurement capability may have been the limiting factor in setting some MCLs. This could be especially true for contaminants with MCLGs set at zero as well as a few contaminants with non-zero MCLGs. When there is no reliable method that is economically and technically feasible to attain the level of the contaminant, EPA promulgates a **Treatment Technique (TT)** in lieu of an MCL. A TT is an enforceable procedure or level of technological performance that public water systems must follow to ensure control of a contaminant.

Finally, the SDWA requires that EPA review each NPDWR at least once every six years and revise, as appropriate. This process is called the Six-Year Review. SDWA specifies that any revision must maintain or increase public health protection.

Limitations with the current regulatory approach have prompted EPA to explore new approaches for addressing health risks associated with contaminants in drinking water. This paper has three components. In Section 2, we identify the opportunities for addressing groups of contaminants within the Safe Drinking Water Act's risk management framework. In Section 3, we suggest factors for grouping contaminants that can potentially be addressed simultaneously as a group. In Section 4, we provide examples of possible groups when using the factors describe in the previous section. In Section 5 we provide a few ideas or potential strategies for addressing contaminants as groups within the context of SDWA, and compare these strategies with traditional regulatory actions.

2. Opportunities for Addressing Groups of Contaminants

Exhibit 2 provides a simplified decision tree showing the main stages of the SDWA regulatory framework. EPA has identified six stages in the regulatory framework which offer opportunities for addressing contaminants as a group; the CCL Stage, Regulatory Determinations Stage, MCLG Stage, MCL Stage, Treatment Technique Stage, and Regulation Review Stage.

CCL Stage: The first opportunity to identify contaminants as groups can occur during the CCL development process. The contaminants on the CCL are priority contaminants for regulatory decision-making and information collection. These contaminants are known or anticipated to occur in public water systems and may require regulation. EPA has mostly listed individual contaminants but has also included groups on past and current CCLs (e.g. organotin compounds, cyanobacterial toxins).

Regulatory Determination Stage: The second opportunity for evaluating contaminants as a group occurs during evaluation of unregulated contaminants from the CCL wherein a decision is made on whether EPA should initiate a rulemaking process to develop an NPDWR for a contaminant group. EPA would need to ensure that the three SDWA statutory criteria for regulatory determinations were addressed. This would involve evaluating the group on the basis of the potential adverse effects of the contaminant group on the health of humans, the frequency and level in water of the contaminant group's occurrence in public drinking water, and whether regulation of the contaminant group presents a meaningful opportunity for reducing public health risks from drinking water.

Regulation Review Stage: Another opportunity for consideration of contaminants as a group could occur when contaminants with existing NPDWRs are reviewed at the six-year intervals specified by the SDWA. Groupings could be based upon current health effects assessments, changes in technology, and/or other factors that provide a health or technical basis to support proposal of a regulatory revision that will maintain or strengthen public health protection.

The following three stages also offer opportunities for consideration of groups of chemicals. These differ from the preceding three examples because they apply to the development of an NPDWR.

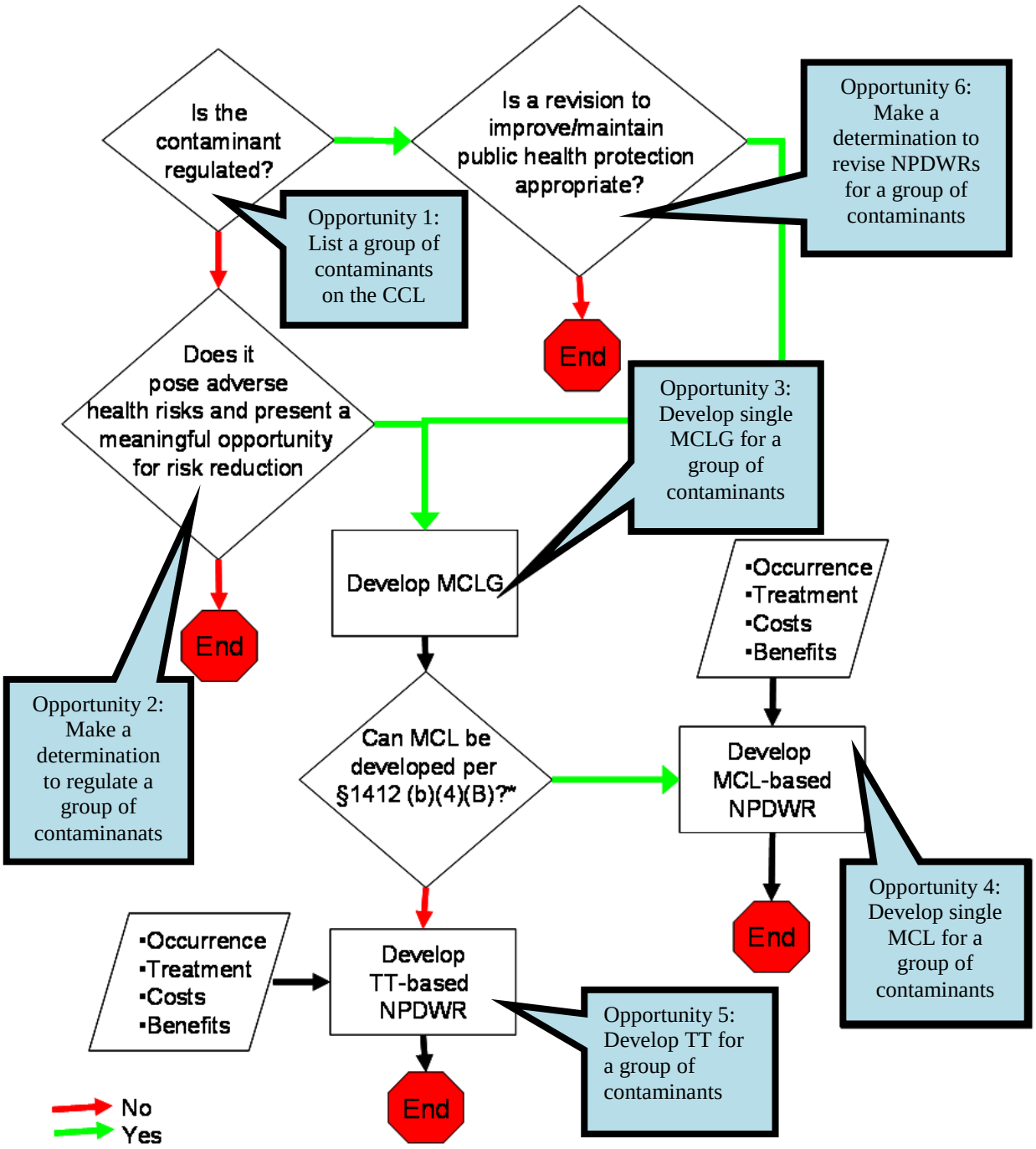
MCLG Stage: It is possible to develop a single MCLG public health goal for a group of contaminants instead of individual contaminant MCLGs. The group public health goal would serve the same function as an MCLG and might be called a Group MCLG. There is precedence

for EPA to set MCLGs that may be considered Group MCLGs. For radionuclides, EPA established a group MCLG of zero for the alpha-emitters as well as beta photon/particle emitters. EPA could have established individual MCLGs of zero for each component contaminant, but concluded that "[d]espite differences in radiation type, energy, or half-life, the health effects from radiation are identical, although they may occur in different target organs and at different activity levels" (56 FR 33050, July 18 1991 at p. 33079). **MCL Stage:** A Group MCL can also be established. There are several examples where the agency has used this approach (the MCLs for trihalomethane and haloacetic acids and total coliforms.) This approach is specially suited for contaminants for which data are not sufficient to develop individual MCLs. (USEPA, 1998; 63 FR 69390, December 16, 1998).

Treatment Technique (TT) Stage: Development of TTs that reduce contaminant levels for an entire group when it is not economically or technologically feasible to ascertain the level of the contaminants in the finished products are also a potential approach for addressing a group of contaminants. An example of a TT EPA developed to address multiple contaminants in drinking water, is the Long-Term 2 Enhanced Surface Water Rule (LT2ESWTR), which includes a requirement for systems having uncovered finished water storage to either (1) cover the finished water storage facility or (2) treat the discharge of the uncovered finished water storage facility that is distributed to consumers to achieve inactivation and/or removal of 4-log virus, 3-log Giardia lamblia, and 2-log Cryptosporidium (USEPA, 2006; 71 FR 654, January 5, 2006).

If a Group MCLG can be developed for a set of contaminants, then presumably the MCL or TT standard will also apply to the group as a whole. As noted above, however, it is also conceivable that a set of contaminants can have individual MCLGs, but a common enforceable standard that applies to the whole group such as a Group MCL or TT.

Exhibit 2. Opportunities for Grouping Contaminants within SDWA



* EPA promulgates an MCL, if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems [SDWA §1401(1)(c)(1)]

3. Factors for Grouping Contaminants

When considering multiple contaminants as groups, certain guiding principles should be considered. These principles might include the following:

1) Groups should be formed and addressed in a manner that will ultimately be protective of public health.
2) Groups should be formed and NPDWRs promulgated in a manner that is consistent with the requirements of SDWA.
3) The NPDWR to address groups should be written to assure combined exposure of the contaminants within the group should not exceed a the threshold of concern for health effects
4) The group approach should be used only when it is more adventitious for PWSs to diagnose and mitigate the risks collectively for the group rather than each contaminant individually
5) The actions to address groups must consider the cost-effectiveness and ease of implementation for the public water utilities and primary agencies.

Factors that should be considered when evaluating whether the guiding principles would be met by the group approach could include:

- Similar Health Effects
- Same Analytical Method
- Similar Treatment/Control Processes
- Occurrence with other chemicals

The use of each of these factors to form groupings is discussed in the following sections:

Health Effects – This factor may provide the key basis for developing a group NPDWR. As noted earlier, EPA has regulated groups of contaminants based upon a common health effects endpoint (e.g. PCBs, Radionuclides) in the past. EPA is working on methodologies to assess the cumulative health risks of mixtures of contaminants, however there are a number of technical challenges in preparing these cumulative assessments. While the Agency works to produce cumulative risk assessments, the Agency could group contaminants based on similar toxicological profiles or common health endpoints. Exhibit 3 shows some examples:

Exhibit 3: Examples of Health Effects-Based Groups
Chemicals with similar toxicological profiles: • Nitrosamines • PFOS/PFOA/PFCs
Chemicals with common health effects/endpoints • VOCs (cancer) • Antibiotics - suppression of probiotics/developing antibiotic resistance strains • Radionuclides (cancer)

- Cholinesterase Inhibiting Pesticides

Treatment – Treatment technologies could also be used as a factor in grouping contaminants for regulation. Contaminants that are removed by the same treatment technologies at similar control points may be likely candidates for a grouping by a treatment technology.

In developing costs and defining operating conditions and compliance criteria for a treatment technique (if used), it will be necessary to consider factors such as the type and amount of other contaminants that may be preferentially removed (or interfere with removal of the targeted contaminants) and water quality parameters that may reduce treatment efficiency (temperature, pH, etc.). Exhibit 4 illustrates some examples of treatment based groups.

Exhibit 4: Examples of Treatment Based Groups

Chemicals that can be removed by the same treatment techniques.

- **Contaminants removed by Granular Activated Carbon (GAC) –** can remove a wide spectrum of organic contaminants, but is ineffective for most inorganic contaminants, pathogens and for some organic contaminants such as vinyl chloride.
- **Contaminants removed with aeration –** aeration can remove most volatile contaminants (VOCs, radon) but is ineffective for most synthetic organic, microbiological and inorganic contaminants.
- **Contaminants removed with Membranes – High pressure** membranes provide a barrier against most contaminants except low molecular weight compounds and some dissolved contaminants (e.g., radon). Low pressure membrane technologies such as microfiltration and ultrafiltration can also provide barriers to a wide range of contaminants, however because these filtration systems have an increasingly larger pore size they are comparatively less effective.

Analytical Methods - EPA assesses analytical feasibility in establishing MCLs for contaminants and must consider the costs of monitoring and testing as part of the health risk reduction and cost analysis for a proposed drinking water regulation. Monitoring costs can be significant on an individual and/or national basis for up to 150,000 public water systems.

Many contaminants can be measured with the same analytical method at a lower cost than using a different, single-analyte method to measure each contaminant. Therefore, it can be more efficient if several contaminants within a group can be measured with a common method especially with a full scan. For example, EPA method 524.3 in full scan mode can be used to measure 31 regulated and several unregulated VOCs with individual quantitation limits of ~1 ug/l or less; EPA method 525.2 can be used to measure 23 regulated SOCs with similar quantitation limits (see Exhibit 5 for details).

Exhibit 5: Examples of Analytical Method That Can Measure a Number of Contaminants in a Group *(Italics indicate unregulated CCL3 contaminants*, all others are regulated)
<u>VOCs – by EPA Method 524.3</u> benzene, carbon tetrachloride, chlorobenzene, 1,2-dichloroethane, 1,1-dichloroethylene, cis-1,2-dichloroethylene, *1,1*- dichloromethane, 1,2-dichloropropane, ortho-dichlorobenzene, para-dichlorobenzene, trans-1,2-dichloroethylene, ethylbenzene, styrene, tetrachloroethylene, toluene, 1,1,1-trichloroethane, 1,1,2-trichloroethane, trichloroethylene, xylenes (total), vinyl chloride *bromomethane. 1,3-butadiene, sec-butylbenzene, chlorodifluoromethane, bromochloromethane, chloromethane, dichloroethane, MTBE, n-propylbenzene, 1,1,1,2-tetrachloroethane, 1,2,3-trichloropropane*
<u>SOCs –by Method 525.2</u> Alachlor, atrazine, benzo[a]pyrene, chlordane, di(2-Ethylhexyl)adipate, di(2-ethylhexyl)phthalate, Endrin, Heptachlor, Heptachlor epoxide, hexachlorobenzene, hexachlorocyclopentadiene, Lindane, Methoxychlor, Simazine, PCBs [arochlors], pentachlorophenol, Toxaphene *alpha-hexachlorocyclohexane (HCH), Metolachlor, Molinate, Permethrin, Ethoprop, Fenamiphos*
<u>SOCs –by Method 515.4</u> Carbofuran, Dalapon, 2,4-D, Dinoseb, pentachlorophenol, 2,4,5-T, Oxamyl, Pichloram, *3-hydroxycarbofuran*

<u>Occurrence</u> - Known occurrence or substantial likelihood that the group will occur in public water systems with a frequency and at levels of public health concern is one of the SDWA criteria for making a determination to regulate contaminants.

Finished water data are preferable to ambient or source water data because such data reflects occurrence after removal by existing treatment processes and also reflects any increases or reactions associated with existing treatment processes (e.g., disinfection/oxidation

Examples of known occurrence data include:

- Finished water (FW) data for regulated chemicals and unregulated chemicals from nationally recognized data sources.

- Finished water data for PWS that have been reported to States, other limited sources of FW data, and possibly finished water data estimates from source water data and treatment information (i.e., USGS NRECs, etc.)

EPA may not have finished water data for a number of contaminants being considered as groups. Therefore, limitations in the type of occurrence data and monitoring schemes may make it difficult to identify the magnitude of the individual contaminants in the group. However, due to the type of contaminant, there may be a substantial likelihood that the contaminant or group may occur in drinking water. For example, if EPA were to revise the standard for a regulated pesticide and it's degradates as a group, most of the occurrence data collected may be for the regulated parent, not it's degradates. EPA may only have supplemental occurrence data that link the parent and degradate occurrence. EPA may have a difficult time in quantifying the occurrence for the degradates. However, the group could still be addressed as a group because there would be a "substantial likelihood" that the degradates occur in PWSs due to the regulated parent's occurrence profile. Exhibit 6 displays examples of occurrence and substantial likelihood based groups.

Exhibit 6: Examples of Occurrence Based Groups

Known occurrence w/ finished water data:	Substantial likelihood to occur in public water systems include:
• Mixtures of other chemicals that are used/applied concurrently (e.g. pesticides/herbicides applied to the same crops, explosives/munitions, etc.) • Mixtures of parent compounds and their degradates (triazines and their degradates; chloroacetanilides and their degradates)	• Personal care products and/or pharmaceuticals with monitoring data showing occurrence in WWTP discharges. • Synthetic chemicals and their analogs that may be substituted once the original chemical is regulated and are likely to have similar physical/chemical properties and health effects

4. Identification of Groups

EPA evaluated the unregulated contaminants listed on the CCL 3 and the contaminants that are regulated with an existing national primary drinking water regulation to identify the broad number of possible groups as illustrated in Exhibit 7. EPA identified a universe of approximately 20 contaminant groups ranging from broad categories (such as all VOCs, SOCs or IOCs) to more narrow categories (such as carbamates, estrogenic compounds, etc.) As the possible groups list was being developed, we included additional unregulated contaminants (not on CCL3) into the group. Several pesticide groupings, such as carbamates and organophosphates, contain chemicals that are regulated and on CCL 3, but also contain chemicals not listed on CCL3. We included these in the preliminary evaluation because they have been considered as groups by other EPA program offices.

Next, EPA evaluated each of the contaminants listed on CCL 3 and Six Year against the following factors (1) the critical health endpoint(s), (2) the various treatments that can be used to treat each contaminant, and (3) the various analytical methods that can be used to measure the contaminant. EPA did not evaluate occurrence of these contaminants for this evaluation because

of the limited data available particularly for the unregulated contaminants under consideration. Occurrence will be further evaluated for those groups that EPA identifies as warranting further evaluation.

Exhibit 7. Possible Groups	
• Volatile Organic Compounds • Synthetic Organic Compounds • Inorganic Compounds • Carcinogenic VOCs • Non-carcinogenic VOCs • Pesticides • Carbamates • Organophosphates • Chloroacetanilides • Triazines • Conazoles	• Disinfection Byproducts • Nitrosamines • Perfluorinated compounds (PFOS/PFOA/PFCs) • Estrogenic Compounds • Androgenic Compounds • Pharmaceuticals • Antibiotics • Cholinesterase Inhibitors • Thyroid Inhibitors

Based on the premise that a viable group has as many factors as possible in common (e.g. health, treatment, analytical methods, etc), EPA then identified the contaminants that fell within a certain group against the critical health endpoint, type of treatment, and analytical methods to identify potentially viable groups. Those groups that had more factors in common represented potentially viable groups whereas those having limited commonalities are not likely to be viable groups. Exhibit 8 illustrates an example of potential groupings that have commonalities within the factors and could possibly be considered for regulatory development. The groups listed in Exhibit 8 had similar health effects, common analytical methods, and common treatment technologies or control processes.

Exhibit 8. Groups for Potential Regulatory Development in the Near Term			
Factors	Carcinogenic VOCs (16)	Nitrosamines (6)	Chlorinated DBPs (several)
Similar Health Effect Endpoints?	MCLG is zero for regulated VOCs. Health endpoints are based on cancer for all VOCs.	Common health effect (cancer, MCLG = 0 for multiple nitrosamines)	Common health effect (cancer, MCLG = 0)
Common Analytical Method (s)?	524.2, 524.3, 502.2 remove most of the VOCs.	Common analytical method - 521	Common analytical methods
Common treatment or control process	Effective treatment technologies are Aeration and GAC.	Treatment technologies are RO, AOP/Ozone.	Treatment technique approach to remove DBP precursors (TOC)

Exhibit 9 displays an example of potential groups that met some of the factors such as common health effects, but would need additional analytical methods and treatment information before we could move forward with regulatory action.

Exhibit 9. Groups for Future Consideration*			
Factors	PFOA/PFOS/ PFCs(7)	Organophosphates (31)	Carbamates (11)
Similar Health Effect Endpoints?	Similar health effects - PFOS/PFOA may be index chemicals for other PFCs.	Common health effects – cholinesterase inhibition	Three have cancer critical endpoints, cholinesterase inhibition for the rest.
Common Analytical Method (s)?	Analytical methods for PFOS/PFOA.	Analytical methods for 4 compounds, need methods for the rest.	Analytical methods for 3 compounds, need methods for the rest.
Common treatment or control process	Effective treatment technologies may be GAC/PAC and RO/NF.	Effective treatment technologies are generally GAC/PAC and RO/NF for pesticides.	Effective treatment technologies are generally GAC/PAC and RO/NF for pesticides.
*Additional groupings listed in exhibit 7 may also be considered in the future. Some of these groups have major challenges and/or data gaps that would have to be addressed before moving forward.			

The groups listed in Exhibit 9 have some commonalities, such as health effects (i.e. organophosphates), but most do not have analytical methods. The example groupings listed in the exhibits are based upon a very preliminary evaluation of the factors. A more detailed evaluation would have to be performed to determine which of the possible groupings represent the most viable for regulatory action.

5. Addressing Contaminant Groups

This section discusses potential strategies for addressing groups of contaminants within the SDWA Risk Management framework and the existing approach. Developing regulations for contaminant groups addresses EPA's two sets of concerns regarding the current process of developing regulations. First, developing an MCLG or similar health-based goal at the group level will more accurately incorporate risks of exposure from multiple contaminants that may be present in drinking water. USEPA (2000)[1] describes a variety of different risk assessment

[1] USEPA. 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002. Washington, D.C.: U.S. Environmental Protection Agency.

methods for either whole mixtures or a subset of the mixture components depending on availability of data.

The fact that some contaminants, such as pesticides and degradates and disinfection byproducts, are likely to occur raises a concern regarding the need for cost-effective regulation that minimizes uncertainty among utilities and their consumers. Promulgating separate rules for individual contaminants that are potentially occurring instead of regulating them in a simultaneous or group manner can lead to water systems making capital investments decisions that may not be the right long-term compliance decisions.

Several ideas or approaches to MCLG and MCL or treatment technique development are presented below. The first deals with single chemical assessments such as those used for current drinking water regulations. The other four are examples of possible approaches for simultaneously evaluating multiple components of a mixture of contaminants and possible regulatory implications. These approaches permit customization of the assessment for specific contaminants and their concentrations that might be found at a drinking water facility.

There are challenges associated with applying each of the following ideas on a national basis within the SDWA regulatory framework. One challenge is the need to determine the best way to deal with chemicals in a group that includes both non-carcinogenic and carcinogenic effects. Another challenge is how to craft approaches could be applied in the context of a maximum contaminant level or treatment technique requirements and could be feasibly implemented by the regulated systems.

In applying any of the following approaches to regulated contaminants, EPA would need to ensure that any revisions maintain or provide for greater protection of public health. If EPA were to consider unregulated compounds for any approach, it would need to meet the three SDWA statutory criteria for regulatory determinations.

a. Standard Approach

Applying the traditional approach to regulating groups of contaminants would result in individual MCLGs and MCLs, or TTs if MCLs were not feasible. For example, Exhibit 9 illustrates how MCLs could be revised for a group of regulated carcinogenic contaminants that all have an MCLG of zero and a common analytical method and treatment. If the current MCLs for this group were based on analytical feasibility and analytical method improvements (since the standards were set) indicate a lower feasible level of measurement (referred to as the practical quantitation limit or PQL), it may now be feasible to lower all of the MCLs in this example to 0.5 μg/L. It might also be possible to establish a Group MCL based on analytical or treatment feasibility to limit total exposure among populations exposed to mixtures of the carcinogenic contaminants to a level that would be more protective than the combination of the current individual MCLs.

The regulatory development steps under the traditional approach would be:

- Identify new Practical Quantization Limit (PQL)/Minimum Reporting Level (MRL) values based on studies of analytical methods
- Determine whether treatment is feasible as low as the PQL/MRL

- Estimate occurrence for an MCL set equal to the PQL/MRL as well as alternative MCL values above the PQL/MRL to determine potentially affected systems and exposed populations from the available monitoring data
- Perhaps establish a Group MCL based on analytical or treatment feasibility to limit total exposure among populations exposed to mixture of co-occurring carcinogenic VOCs (e.g., the Total MCL could be the sum of the minimum reporting limits across the co-occurring contaminants, which would then have to be less than the sum of the component MCLs) in order to meet the requirement that the group value would have to be more protective of health than the current individual MCLs
- Estimate compliance costs for the entry points and systems affected at varying MCLs and benefits of reduced contaminant exposure
- Make a determination of whether the benefits justify the costs at the MCL set equal to the PQL/MRL

Revising regulations for a subset of regulated carcinogenic compounds and possibly considering several unregulated carcinogenic compounds could constitute a meaningful opportunity for health risk reduction and might simultaneously address both the health risk from the group and the regulatory cost-effectiveness/uncertainty concerns of co-occurring contaminants noted in Section 2. Under this scenario, affected utilities might make a single decision to optimize treatment design to lower levels of co-occurring contaminants and more practically achieve protection from all contaminants in the group. Using this approach would allow the agency to update the health assessment so that it reflects the most recent agency cancer risk measures, which in many cases have changed since the time of the original regulation.

Exhibit 9. Current NPDWRs for Carcinogenic VOCs

Contaminant	MCLG (μg/L)	MCL[1] (μg/L)	Potential to Lower PQL[1] (ppb)	Occurrence Estimates Systems[2]	Occurrence Estimates Population[2] (millions)
Benzene	0	5	0.5	123	0.5
Carbon Tetrachloride	0	5	0.5	118	0.75
1,2-Dichloroethane	0	5	0.5	82	0.27
Dichloromethane	0	5	0.5	579	3.4
1,2-Dichloropropane	0	5	0.5	61	0.5
Tetrachloroethylene	0	5	0.5	519	14.6
Trichloroethylene	0	5	0.5	388	12.9
Vinyl Chloride	0	2	0.5	49	0.76

1. The MCL for each contaminant is limited by analytical feasibility, thus each MCL is equal to the PQL for that contaminant. As part of the second Six-Year Review, EPA determined that there is potential to lower the PQLs for each contaminant to at least 0.5 μg/L.
2. The occurrence data are those reported as part of the second Six-Year Review and does not represent national occurrence as not all States provided occurrence data. The estimates are based on system-level means of monitoring data for each contaminant. The estimates indicate the number of systems that have means greater than 0.5 μg/L when nondetection results are assigned a value equal to half their minimum reporting level values. Actual compliance is determined at entry points to the distribution system. Occurrence results and population served may differ across entry points within a system.

b. Hazard Index (for non-carcinogenic compounds)

The Hazard Index (HI) is a weighted sum of the exposure measures for the mixture component chemicals to evaluate a system's risk of exposure. It is the sum of the ratios for the individual members of the group of chemicals' exposure level to their health benchmark (RfD or cancer slope factor-based) allowable level. The goal of this component-based assessment is to approximate what the cumulative risk would be from exposure to a mixture of chemicals from the group. For example, an HI for reproductive toxicity should approximate the concern for reproductive toxicity that result from exposure to multiple non-carcinogenic chemicals encountered simultaneously in drinking water. HI values are specific for a particular health endpoint, and HI values for different health endpoints should not be mixed. Depending upon the availability of data, one or more HI values can be calculated for a group of related chemicals to inform health endpoints of greatest concern, and serve as a basis for identifying a possible MCL. Under an HI approach, the exceedance of an HI of 1 or some other benchmark that considered other exposure sources could trigger a treatment technique as a regulatory response for a given system.

The application of the HI approach is most easily described with an example for a specific water system. In Exhibit 10 below, hazard quotients (HQ) for three different health effect endpoints are calculated for each chemical in a hypothetical group for a given system. The HQ values for each chemical in the hypothetical group are summed for each health effect to determine the groups' HI value. For example, the HQ values for the chemical group sum to an HI = 1.3 for reproductive effects and an HI = 2.1 for neurological effects. An HI > 1 indicates that the combined exposure exceeds the acceptable exposure indicated by the RfD or some other toxicity benchmark and could therefore trigger a treatment technique requirement. The HI for developmental toxicity sums to 0.88, and is within the acceptable range.

The regulatory development steps under HI approach might be:

- Establish "End-point Specific Benchmark Values" for all of the various non-carcinogenic health endpoints (e.g. reproductive, developmental, neurological effects, etc) for compounds A through H (if available or if applicable)
- Determine whether a common analytical method is available for compounds A through H that is sufficiently sensitive to monitor in the range of the benchmark values
- Determine whether it is feasible to measure these compounds in finished water and whether treatment technologies are available to remove the contaminants when they exceed the HI benchmark value
- If feasible to measure and treat, consider establishing an HQ for the compounds that exhibit the limiting non-carcinogenic health effect. In this example the MCL would be expressed as a HQ value. If the HQ value were exceeded for any of the health endpoints, the system would need to install and operate prescribed treatment technologies. .
- Estimate the potential occurrence to determine potentially affected systems and exposed populations for members of the HI group
- Estimate compliance costs for the entry points and systems affected and benefits of reduced contaminant exposure for the MCL or TT approach
- Make a determination of whether the benefits justify the costs.

There are several outstanding challenges in applying the HI approach on a national basis within the SDWA regulatory framework. One challenge is determining an approach to deal with

chemicals in a group that has both non-carcinogenic and carcinogenic effects (since this HI approach primarily applies to non-carcinogenic compounds). Another challenge would be to determine how the HI approach could be applied in the context of a treatment technique requirement that could be implemented by affected systems.

Exhibit 10. Hazard Index Approach for a Group of Hypothetical Chemicals

		Reproductive Effect		Developmental Effect		Neurological Effect	
Contaminant	**Detected Conc.**	**Benchmark (ug/L)**	**HQ**	**Benchmark (ug/L)**	**HQ**	**Benchmark (ug/L)**	**HQ**
A	0.03	0.3	0.1	0.05	0.6	0.15	0.2
B	0.004	0.01	0.4	0.1	0.04	N/A*	N/A
C	0.02	0.1	0.2	N/A	N/A	0.05	0.4
D	0.03	N/A	N/A	0.5	0.06	0.05	0.6
E	0.05	0.5	0.1	N/A	N/A	N/A	N/A
F	0.008	N/A	N/A	0.1	0.08	0.01	0.8
G	0	0.08	0	0.005	0	N/A	N/A
H	0.05	0.1	0.5	0.5	0.1	0.5	0.1
Hazard Index (HI)			**1.3**		**0.88**		**2.1**

***Value not available**

c. Relative Potency Factor Approach

Groups of chemicals known to cause adverse effects by a common mode of action can be evaluated by using relative potency factors (RPFs). This approach can also be applied to chemicals that can be inferred to have a common mode of action because of similarities in structure and the nature of the effect. The approach relies on both the existence of toxicologic dose-response data for at least one component of the mixture (referred to as the index compound). Scientific judgment must be used to determine the relationship of the toxicity of the other individual compounds in the mixture to the toxicity of the index chemical. The toxicity of each chemical in the group is predicted by comparing its dose-response to the dose-response of the index compound. The exposure level of each compound is adjusted by its toxicity relative to the index compound. This scaling factor or RPF is based on an evaluation of the results of a set of toxicologic assays or analyses of the chemical structures. This RPF represents the relative toxicity with respect to the index compound. For example, if compound B is judged to be one-tenth as toxic as the index compound (compound A), i.e., it requires ten times the exposure to cause the same toxicity, then the RPF for compound B is 0.1. If all components of the mixture are assumed to be as toxic as the index compound, then all of RPFs would be 1.0; if all of the related compounds have negligible toxicity even at exposures > 10 times the index chemical, all of their RPFs could be assigned a value of 0.

In the RPF approach, the product of the measured concentration of each compound times the RPF for that compound is the adjusted concentration. These adjusted concentrations are summed to express the mixture exposure in terms of an equivalent exposure to the index compound; risk can be quantified by comparing the mixture's equivalent dose in terms of the index compound to the dose-response assessment of the index compound. The RPFs must be defined with recognition of the scope of toxicologic effects that are covered, the degree of similarity in chemical structure, and mode of action that can be inferred from the summation of the adjusted exposure levels. If one or more of the chemicals had effects that occurred at doses below those reflecting estrogenicity this approach would be able to include those chemicals in the estrogenicity analysis but would also have to consider the other adverse health effects when applying the RFP data.

The RPF approach could be used to develop a group standard if sufficient data are available to support the relative toxic benchmark determinations for the compounds in the group. In Exhibit 11, several hypothetical compounds with the same health endpoint are considered as a group by developing RPFs based upon the toxic benchmark concentration in drinking water for a given system. Compound A is the index chemical. The adjusted concentrations are developed for each compound and summed to a Chemical A Equivalent Dose. The total Chemical A Equivalent Dose is compared to the toxicity endpoint for Compound A (i.e., 0.35 ug/L) to determine whether it exceeds the toxic dose.

Exhibit 11. Application of Relative Potency Factors for Hypothetical Compounds

Estrogenic Compound	Toxic Benchmark (ug/L)	RPF	Concentration (ug/L)	Adjusted Concentrations (ug/L)
Chemical A*	0.35	1	0.3	0.3
Chemical B	0.70	0.5	0.12	0.06
Chemical C	0.18	2	0.05	0.1
Chemical D	0.35	1	0.1	0.1
Chemical E	0.35	1	0.02	0.02
Chemical F	0.035	10	0.01	0.1
Chemical G	0.035	10	0.08	0.8
Chemical **A Equivalent Dose**				**1.48**
*Index chemical				

The regulatory development steps under the RPF approach might be:

- Develop an MCLG for Chemical A
- Determine whether a common analytical method is available for Chemicals A through G that is sufficiently sensitive to monitor in the range of the MCLG

- Estimate occurrence for an MCL set equal to the MCLG to determine potentially affected systems and exposed populations for members of the RPF group
- Determine whether an appropriate treatment method is available, and whether an MCL equal to the MCLG is feasible
- Estimate compliance costs for the entry points and systems affected at varying MCLs and benefits of reduced contaminant exposure
- Make a determination of whether the benefits justify the costs at the MCL.

d. Summation Cancer Risk (Primarily a Tool for Benefits and Costs)

Chemicals that are structurally related and cause the same tumor types in the same organ can be inferred to cause cancer by the same mode of action. The carcinogenic effects of these chemicals can be assumed to be additive. Carcinogenic risks can be summed to determine the overall risk for the entire group. For example, contaminants in Exhibit 12 are structurally related and all produce the same type of liver tumors via a mutagenic mode of action. Therefore, it is reasonable to sum the cancer risks from the group of chemicals.

Cancer risks for individual contaminants that have a similar chemical structure and produce the same type of tumor on the same organs (e.g. liver tumors) are illustrated for a hypothetical group of contaminants in Exhibit 12. The exhibit illustrates that the sum of the cancer risks for the group is greater than most of the individual chemicals within the hypothetical group. The total cancer risk for the group would be considered in the evaluation of benefits of alternative MCLs or treatment techniques. The benefits for the group of contaminants may be greater than the benefits for the individual contaminants.

Exhibit 12. Hypothetical Example to Illustrate the Summation of Liver Cancer Risk

Carcinogenic Contaminant	Cancer Slope Factor $(mg/kg\text{-}day)^{-1}$	Concentration (ug/L)	Cancer Risk at Concentration*
A1	21×10^{0}	0.015	9.3×10^{-6}
A2	5.4×10^{0}	-	-
A3	1.5×10^{2}	0.103	4.4×10^{-4}
A4	2.2×10^{1}	-	-
A5	2.1×10^{0}	0.027	1.6×10^{-6}
Total Cancer Risk			4.5×10^{-4}

*Cancer risk for a carcinogen with a mutagenic mode of action is calculated from the cancer slope factor using the following formula:

Cancer Risk = Cancer Slope Factor x DW Intake/kg bw x CW

where:
CSF = The Cancer Slope Factor
DW = Drinking water intake.
bw = body weight (Kg)
CW = A concentration in water of 0.001 mg/L (1 µg/L)

All of the MCLGs for the contaminants would be zero (0) as is typically the case for carcinogens. Because the MCLGs (0) cannot be achieved, a regulatory approach based on what is feasible to achieve for the group would be used. Treatment effectiveness and the sensitivity of an analytical method capable of simultaneously measuring the members of the group would be factors used to determine the feasible level upon which to base an MCL or treatment technique. The total cancer risk for the group of contaminants would serve as a consideration of the benefits and cost effectiveness of regulation of the group, as well as identifying an appropriate MCL or treatment technique within the context of the standard approach previously discussed.

e. Treatment Barrier Approach

A treatment barrier approach may be appropriate when a group of contaminants pose a health concern but it is not economically or technologically feasible to ascertain the level of the contaminant(s) in drinking water. This condition may be due to a variety of factors such as insufficient sensitivity or precision of available analytical methods, infrequency and variation by which the contaminants occur, or difficulties in interpreting the risk implications from measurement for multiple contaminants; and the availability of technologically and economically feasible treatment technologies that can mitigate the exposure concern.

A treatment barrier approach can take a variety of forms depending upon the characteristics of the group of contaminants of concern and the technologies available to reduce such exposure. Under a treatment barrier approach EPA might require the application of a particular technology with specified design and operating conditions for a subset of public water systems deemed to be vulnerable by defined characteristics. Another approach might be requiring public water systems with defined vulnerability characteristics to meet indicator performance criteria which if achieved would trigger actions (from a designated toolbox of options) to mitigate the group contaminant exposure concern.

For example, EPA could use a treatment technique approach to remove disinfection byproduct precursors indicated by total organic carbon (TOC). Additional TOC removal prior to disinfection could substantially reduce exposure to DBP risk.
EPA could use TOC as performance metric (e.g., lower concentration bound and/or percent removal) because it is easy to monitor and allows for treatment choice flexibility (e.g., enhanced coagulation, oxidation/filtration, GAC, or membranes could be used to achieve TOC performance metric). Use of any of above technologies could also provide reduction of other contaminants.

The regulatory development steps that would be taken to inform the applicability of the treatment barrier approach would include:

- Define the MCLG for the group at large and/or for MCLGs for contaminants within the group.
- Determine that it is not economically and technologically feasible to ascertain the level of contaminants within the group

- Determine that is economically and technologically feasible for utilities to mitigate exposure from the contaminant group.
- Identify monitoring parameters that could be measured and reflect the efficacy of the treatment technique at removing the group contaminants of concern.
- Develop a strategy that would link the monitoring strategy to health effects in order to demonstrate an increase in public health protection.
- Develop different options by which utilities would be required to install and operate the treatment barrier and estimate the associated costs and benefits for each option
- Compare the benefits with costs to inform the best option.

6. Conclusion

This paper provides some initial thoughts of possible approaches to address contaminants as groups and factors for grouping contaminants together in the context of the SDWA regulatory framework. There may be other approaches and factors that EPA should consider and evaluate. In addition, the approaches and factors considered may differ with the contaminant group. EPA looks forward to hearing the public's ideas about the various approaches and factors that should be considered in addressing contaminants as group(s) and how to better protect public health for American consumers of public drinking water.

Abbreviations and Acronyms used in this document

CCL -- Contaminant Candidate List
GAC -- Granular Activated Carbon
HRRCA – Health Risk Reduction and Cost Analysis
HI – Hazard Index
HQ -- Hazard Quotient
IOC – Inorganic chemical
MCL -- Maximum Contaminant Level
MCLG -- Maximum Contaminant Level Goal
MRL -- Minimum reporting Level
NPDWR -- National Primary Drinking Water Regulation
PFC – Perfluorinated Compound
PFOA - Perfluorooctanoic Acid
PFOS - Perfluoroctane Sulfonic Acid
PQL -- Practical Quantitation Limit
RFP -- Relative Potency Factor
SDWA -- Safe Drinking Water Act
SOC -- Synthetic Organic Chemical
TOC – Total Organic Carbon
TT -- Treatment Technique
UCMR -- Unregulated Contaminant Monitoring Regulation
VOC -- Volatile Organic Chemical